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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,455	05/09/2001	Arthur J. Blume	2598-4004US1	5124

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	
MAIL DATE	**DELIVERY MODE**
07/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/852,455	BLUME ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 7-56* is/are pending in the application.

4a) Of the above claim(s) *2,3,13,14 and 17-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 7-12 and 15-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/2006 has been entered.

Status of Claims

Claims 1-4 and 7-56 are pending in the application.

Claims 2-3, 13-14 and 17-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species.

Claims 1, 4, 7-12 and 15-16 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1, 4, 7-12 and 15-16, as amended, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office actions, 3/23/04, 12/22/2004 and 9/12/2005.

Response to Arguments

Applicants state that there are a number of examples of methods involving binding of proteins where a detailed structural description of the binding partners is not given. For example U.S. Patent 4,376,110 directed to a "sandwich" immunometric assay for ligands in fluids. The claims of this patent do not restrict the structure of the binding sites of the monoclonal antibodies used in the method. The method claimed is generally applicable to use with antibodies with any specificity. Another example is U.S. Patent 6,287,785 directed to a homogeneous immunoassay process using multiple antibodies. Again, the claims do not limit the structure of the binding site of the antibody directed to the ligand of interest, the antibody may have any specificity that is useful for the particular embodiment. In the present application, since the method claimed is directed to identifying the binding partner and the method is applicable to identifying a broad range of potential binding

partners the Applicants can hardly be required to provide a structural description of a substance that is not yet identified.

In response, it is well settled that each case must be determined on its own facts in determining the adequacy of 112 disclosures. The two cited patents recite specific compounds i.e., antibody albeit does not recite the structure. The instant specification does not describe library, which contains the different expressed amino acid sequences, let alone the precursor of the different expressed amino acid sequences. It is not apparent from the disclosure from where the different amino acid sequences are expressed i.e., whether from the numerous genes expressed in different tissues or cells. Even a single cell expressed already billions of amino acid sequences. The disclosure does not provide guidance or direction by which the expressed amino acids length are restricted only to about 20-40-mer, especially the precursor of these amino acid sequences.

To satisfy a written description requirement for a claimed genus a sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation

between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure indicates that the applicants have invented species sufficient to constitute the gen[us]. Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004). See also University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 7, 9-12 and 15-16, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 1, step (a) is confusing as to whether the library is comprised of an already different expressed amino acid sequences of from about 20 to about 40 amino acids in length. Is the library an isolated expression product? Furthermore, it is not clear as to what constitutes a plurality of these sequences in a library. Is a library different from the plurality or are these synonymous? It is not clear as to the "common" amino acids in a motif, especially in the absence of any structure/formula of the motif. It appears that "common" and motif are one and the same it. Is it the common or motif that is being compared with the known amino acid sequences of a genome? The claimed "partner precursor", within the claimed context is unclear since there is no differentiating features/characteristic with that of the binding partner. Clarification/explanation is required.

2. Claim 16 is unclear in what respect the amino acids are considered contiguous. Is it in terms of primary or tertiary structure?

Claim Rejections - 35 USC § 102

Claims 1, 4, 7, 9-12 and 15-16, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Ivanenkov et al (The Journal of Biological Chemistry, 6/16/95) for reasons set forth in the last Office action, 12/22/2004 and 9/12/2005.

Response to Arguments

Applicants state that as amended herein, claim 1 now contains the element from claim 6 requiring the size of the amino acid sequence to be "of from about 20 to about 40 amino acids in length." The amino acid sequences used in Ivanenkov are 15 amino acids in length (see legend to Table 1, page 14653 of Ivanenkov).

In response, Ivanenkov at Table 1, page 14563 as cited by applicants, states:

> [The] Amino acid sequence alignment of S-100b binding peptides. Conventional single letter amino acid code was used: The bacteriophage library contains a random sequence of ***15 amino acids, which is flanked by [AE] at the amino terminus, and six consecutive praline residues (P6) at the carboxyl terminus*** (Devlin et al., 1990). Position of the eight amino acids contained within the common motif is numbered at the top. The residues in the inserts satisfying this consensus motif are highlighted and shown by capital letters, and the motif common for the sequences in groups (I-IV) is shown schematically at the bottom of the group IV (+, positively charged residue; 0, hydrophobic residue; hydrophilic residue; X, variable residue). Sequences in brackets indicate invariable sequences present in all random peptide pIII-fusion protein isolates. If greater than one, the number of occurrences of a particular insert is indicated in parentheses. ***Dashes have been inserted for spacing and do not indicate position of unnamed amine acids.*** (Emphasis added).

Accordingly, Ivanenkov's disclosure of the 15 amino acids with six (6) proline at the carboxy end and (asp-Glu) at the N-terminus (i.e., 23-mer) meet the claimed method wherein the length of the peptide is limited to about 20 amino acid

residues. Furthermore, as stated by Ivanenkov the dashes does not indicate an unnamed amino acids(but are residues present in the natural protein). Ivanenkov further teaches several modifications (reads also on the claimed precursor) that were applied that identifies the natural protein actin capping protein ACP, CapZ (Table II). The claimed precursor will also read on Ivanenkov's description of proteolytic fragmentation of various S-100 target proteins, isolation and characterization of S-100 binding peptides from these proteolytic soups might permit the identification of consensus S-100 binding epitopes within the different S-100 targets (page 14652, col. 1). [See Ivanenkov's reference to the Dedman reference at page 14653, col. 1. Dedman teaches at Table 1, a peptide motif with 25 amino acid residues.]

Claim 15 which recites the motif as 5 to 8 amino acids is fully met by Ivanenkov's motif of eight(8)-mer as shown at Table 1.

Claims 1, 4, 7, 9-12 and 15-16, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Kraft (The Journal of Biological Chemistry, 1/22/1999) for reasons advanced in the last Office action, 12/22/2004. [This rejection was based on the natural proteins and not to its precursor.]

Response to Arguments

Applicants state that Kraft uses amino acid sequences of 7 or 12 amino acids in length (see Table 1 of Kraft).

In reply, attention is drawn to page 1981 of the Kraft reference:

> This distribution was distinct from that of beta6 phage display library screen {Table I) and similar to that reported for linear 15-mer library screens (23).

Thus, while Kraft discloses only the motif of 12 amino acids however, said motif is attached to the longer chain phage.

Claim Rejections - 35 USC § 103

Claims 1, 4, 7-12 and 15-16, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivanenkov in view of Kay et al (6,303,574) for reasons of record, 12/22/2004 and 9/12/2005 or Sahu (The Jrnl. of Immunology).

Response to Arguments

Applicants point out that the abstract of Ivanenkov states "Alignment of the sequence of 44 unique S-100b binding peptides" (emphasis added). There is no disclosure in Ivanenkov teaching or suggesting the use of sequences of 44 amino acids in length to identify a common motif.

Applicants reiterate the argument that in order to establish a prima facia case of obviousness there must be a motivation to combine the references, In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Kay is cited by the Examiner as teaching the use of a random sequence of 9-45 amino acid residues encompassing a consensus sequence in order to improve the binding "selectivity's or specificities." Ivanenkov reports in Table 1 that 80% of the unique sequences had a common motif of 8 amino acids, there is no disclosure that additional amino acids are needed. Therefore one of ordinary skill in the art would have no motivation to combine Ivanenkov with Kay to use a longer length random peptide, such as Applicants peptides of 20 to 40 amino acids, "in order to locate and fingerprint the motif with 'high specificity and selectivity.'

In response, attention is directed again to Table 1 of Ivanenkov, as discussed above. Furthermore, as taught by Ivanenkov this is only the motif that binds but suggests a longer chain sequence.

It is well-settled that there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary

skill in the art. In re Simon 174 USPQ 114 (CCPA 1972). See also kSR International co. v. Teleflex Inc. (decided 4/30/07).

Nonetheless, one having ordinary skill in the art at the time the invention was made would be motivated to use a longer chain peptide of about 40 amino acids in length in the method of Ivanenkov as taught by Kay. Kay discloses at col. 5, lines 20-63 the conventionality of using a random sequence of 9-45 amino acid residues. Kay teaches that this peptide length encompasses a consensus sequence that reflects variations in the motif domain binding selectivities or specificities. Sahu similarly discloses at page 885, Materials and Methods section that long random peptides(27-mer library) adopt a secondary structure more conducive to binding than short peptides. One would have been motivated to use a longer chain peptide in the method of Ivanenkov since Kay teaches that the choice of this conventional length results in a high selectivity/specificity of binding or is more conducive to binding as taught by Sahu. It would be within the ordinary skill in the art to pick and choose the length within the claimed range that would provide an optimized compound from the library, as taught by the different prior art.

No claim is allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yates discloses use of MS to identify amino acid sequences in databases.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
June 21, 2007